



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Washington DC 20204

SEP - 9 1998  
6101 '98 SEP 11 P1:54

Mr. Rob Maltas  
VP Product Development  
The Winning Combination  
1125 Dawson Avenue  
Henderson, Nevada 89015

Dear Mr. Maltas:

This is in response to your letter of August 31, 1998 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that The Winning Combination is making the following claim, among others, for the product "St. John's Emotional Lift:"

"...possess emotionally supportive properties in those individuals who are feeling mildly depressed"

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statements that you are making for this product suggests that it is intended to mitigate, treat, cure, or prevent disease, namely depression. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

Please contact us if we may be of further assistance.

Sincerely,

James T. Tanner, Ph.D.  
Acting Director  
Division of Programs and Enforcement Policy  
Office of Special Nutritionals  
Center for Food Safety  
and Applied Nutrition

978-0163

LET 217

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Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300

FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of Enforcement, HFC-200

FDA, San Francisco District Office, Office of Compliance, HFR-PA140

cc:

HFA-224 (w/incoming)

HFA-305 (docket 97S-0163)

HFS-22 (CCO)

HFS-456 (File)

HFS-450 (file, r/f, OSN#61040)

HFD-310 (BWilliams)

HFD-314 (Aronson)

HFS-600 (Reynolds)

HFS-605 (Bowers)

GCF-1 (Nickerson, Dorsey)

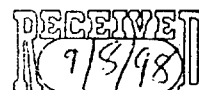
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1125 Dawson Avenue  
Henderson, Nevada 89015  
702-564-9000 FAX 702-564-7829

August 31<sup>st</sup> 1997

Director  
Special Nutritionals  
Center for Food Safety and Applied Nutrition  
FDA  
200 C Street S.W.  
Washington, DC 20204



Dear Sir / Madam:

This is a 30-day notification for a dietary supplement that will be on the market within 30 days. The product name is **St. John's Emotional Lift**. The claims on the 60 and 180 count packages are identical and are:

**"ST. JOHN'S EMOTIONAL LIFT** is a 100% natural herbal supplement designed to provide a naturally supportive lift and help balance the demands of today's emotionally exhausting lifestyle. St. John's Wort is an herb that has been used as a part of traditional herbal medicine for millennia going all the way back to the ancient Greeks. St. John's Wort's primary application in herbal folklore has been as a natural supportive agent to promote feelings of well being. Extensive clinical research has been done in Europe, which has confirmed the properties of St. John's Wort to elevate mood and help to support a positive outlook. In Germany, extracts of St. John's Wort are widely recommended precisely for this purpose. In numerous European clinical studies, St. John's Wort has been confirmed to possess emotionally supportive properties in those individuals who are feeling mildly depressed. Following these clinical studies, our St. John's Wort is standardized to deliver 0.3% hypericin. Additionally, our **St. John's Emotional Lift** contains synergistic nutrients to support and enhance this formula's benefits.

**Caution:** This formula is not intended for use during pregnancy, lactation or by children. Do not overexpose yourself to sunlight while taking this product. St. John's Wort may cause photosensitization. Discontinue use if a rash develops. This product should not be used while taking a prescription antidepressant medication.

*The above statement has not been evaluated by the FDA. This product is not intended to diagnose, treat, cure or prevent any disease."*

Respectfully Submitted,

Rob Maltas  
VP Product Development

also see docket 975-0163